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April 24, 2023

VIA ECF

The Hon. Robert B. Kugler
United States District Judge
USDJ, District of New Jersey
Mitchell H. Cohen Building & U.S.
Courthouse
4th & Cooper Streets, Room 1050
Camden, NJ 08101

Special Master the Hon. Thomas
Vanaskie
Stevens & Lee
1500 Market Street, East Tower, 18th
Floor
Philadelphia, PA 19103

RE: *In re Valsartan, Losartan, and Irbesartan Products Liability Litigation*, No. 1:19-md-2875-RBK-KMW (D.N.J.)

Dear Judge Kugler and Judge Vanaskie:

I write on behalf of the Defendants' Executive Committee to inform the Court that defendants wish to address two agenda topics at the conference with the Court on April 26, 2023, and to set forth our positions on those items.

Case Management Order 32

Manufacturer Defendants. The Manufacturer Defendants will be prepared to discuss CMO 32 generally and their request for short extensions of certain due dates.

Case Management Order No. 32, Section 8.1, sets a deadline of May 30, 2023 for defendants to submit their response to the report of plaintiffs' damages expert, Dr. Rena Conti, with a deadline of May 31, 2023 for the parties to submit a schedule for deposing the damages experts. These deadlines create a number of scheduling conflicts for multiple members of the TPP Trial defense group relating to preplanned events for the Jewish holiday of Shavuot (May 25-27) and preplanned travel for Memorial Day weekend (May 27-29) and the week of Memorial Day. Accordingly, the TPP Trial defendants respectfully request that the May 30 and

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May 31 deadlines be moved by one week to June 6 and June 7, and that the May 31 Case Management Conference likewise be rescheduled at the Court's discretion to June 7 or such date after June 7 as may be convenient for the Court. Defendants' counsel inquired on the morning of Monday, April 23 whether Plaintiffs' counsel have any objections to this request, and Plaintiffs' counsel had not yet responded as of the filing of this letter.

Pharmacy Defendants. The Pharmacy Defendants request that the Court grant limited relief from CMO 32 on "retailer" discovery regarding valsartan.

The Pharmacy Defendants respectfully submit that ordering further discovery on valsartan containing drugs is error. First, discovery closed long ago, and Defendants were previously denied the opportunity take discovery after that deadline. Plaintiffs should be held to the same standard. Second, there are no outstanding document requests to the Pharmacy Defendants. In meeting and conferring with Plaintiffs, the Pharmacy Defendants objected to additional general discovery and requested that Plaintiffs propose specific, rather than abstract, discovery requests so the Pharmacy Defendants could evaluate what was being asked. Plaintiffs never made such specific requests. Third, the expedited production of voluminous, highly proprietary, and complex data by the end of May is untenable.

Although the Pharmacy Defendants continue to respectfully assert that no further discovery from them is necessary or appropriate, given the close of discovery, the Pharmacy Defendants understand the Court intends to push discovery forward. In light of that directive, the Pharmacy Defendants respectfully ask that the Court reconsider the April 21 Order as concerns the Pharmacy Defendants, specifically regarding the scope of the requests and the timing of production.

Discovery from the Pharmacy Defendants concerning the "amounts TPPs paid for VCDs." Because the Pharmacy Defendants are not named as Defendants by any TPP, they are non-parties with respect to any discovery concerning the amounts that the TPPs paid for VCDs. Given the fact that the Pharmacy Defendants are not parties and the TPPs are themselves Plaintiffs, the Pharmacy Defendants submit that this discovery, which covers voluminous amounts of data spanning a ten-year period, is burdensome to produce, and that the burden of producing these data (both in terms of the volume of data, and the significant competitive concerns with producing these data) is not proportional to the needs of this litigation.¹

In addition to the Pharmacy Defendants' concerns regarding burden, there are currently no pending discovery requests from Plaintiffs to the Pharmacy Defendants seeking these data. The Pharmacy Defendants therefore need to meet and confer with Plaintiffs to understand the scope of exactly what is sought and in what form the Pharmacy Defendants can provide it. For

¹ The Pharmacy Defendants previously briefed this issue for the Court in June 2020, and presented the Court with both briefing and affidavits outlining the burdensome nature of this discovery, including that information concerning costs, reimbursement rates and payments for generic drugs such as VCDs is highly proprietary and is treated with the utmost level of sensitivity by each of the Pharmacy Defendants. (ECF No. [479](#).)

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example:

- How general is this request? Does this request refer to all TPPs, or just those in the class or part of the upcoming trials?
- Does this refer to all VCDs for all time or is this reasonably limited by time?
- Can the parties confer and agree upon a format that lessens the Pharmacy Defendants' concerns regarding the competitive nature of the data, or the burden of querying the data?

Moreover, practically speaking, a data query of this volume over this period of time is incredibly difficult and takes time to prepare even once the parameters of Plaintiffs' request are clear. The Pharmacy Defendants respectfully submit that, even were the request clear as of today, pulling these data, reviewing them for data errors or other issues, and producing them within 30 days is not feasible for most, if not all, of the Pharmacy Defendants. (Indeed, producing dispensing data in response to Plaintiffs' previously served discovery took months and, in some cases, required iterative pulls of data to ensure that the parameters and limitations of the requests were met.) Because pharmaceutical pricing is extremely complex, the Pharmacy Defendants cannot simply print a spreadsheet of the "Amounts TPPs paid for VCDs." For many of the Pharmacy Defendants, such a number may not exist for an individual drug or be tracked on a granular level.

Although the Pharmacy Defendants are willing to confer with Plaintiffs on these issues, the Pharmacy Defendants are substantially concerned that meeting a May 30 deadline to pull data reflecting TPP payments is impossible. Further, it does not appear that affording the Pharmacy Defendants additional time to complete this request will impede the progress of this case. The Pharmacy Defendants therefore respectfully request that the Court reconsider its order for production of this data by May 30, and instead order the parties to meet and confer regarding the specifics and scope of this Request, and the timing of production. At a minimum, the Pharmacy Defendants request an additional 45 days to investigate this request, confer with Plaintiffs, and produce this data.

Discovery concerning "Retailers' costs and profits for VCDs." The Pharmacy Defendants with unjust enrichment claims alleged against them² understand that their "costs and profits for VCDs" might have been relevant to Plaintiffs' unjust enrichment claims, which is why the Pharmacy Defendants were puzzled that Plaintiffs never sought this information before the close of general discovery. But Plaintiffs' expert, Dr. Rena Conti, claimed that this information was irrelevant because she did not need information regarding costs (such as cost of the drug) or payments (such as payments made by TPPs) that did not occur directly at the point of sale. Conti Dep. II ([ECF No. 2040-5](#)) 93:18-96:5, 172:22-173:8; *see also* Conti Motion to Exclude Reply ([ECF No. 2110-5](#)) at n.8.

² Humana Pharmacy, Inc. does not have unjust enrichment claims alleged against it, as it is only a defendant in the personal injury complaint, and therefore objects to any production of the cost and profit data requested.

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Understanding the Court wishes the Pharmacy Defendants to produce this unspecified data, it is unclear exactly what Pharmacy Defendants need to produce or why, given Plaintiffs' own expert's testimony that she has the data she needs to calculate profits for retailers. As such, counsel for the Pharmacy Defendants need clarity on what information Plaintiffs actually seek, and need an opportunity to confer with their respective clients to determine the format in which any such data can be produced. (As with TPP reimbursement amounts, not all Pharmacy Defendants necessarily track profits on a per-drug basis, such that there are challenges and complexities to querying and producing the data that Plaintiffs seek.) Because the Plaintiffs' claims against the Pharmacy Defendants are not designated for the first trial contemplated by the Court, affording the Pharmacy Defendants additional time to confer with Plaintiffs and to prepare this data will not delay these proceedings. Thus, for this category of discovery, the Pharmacy Defendants respectfully request that the Court reconsider its order for production of this data by May 30 and instead order the parties to meet and confer regarding the scope of this request and the timing of production.

Production of “previously-redacted retailer identifiers of ConEcoLoss members.”

The Pharmacy Defendants have two concerns regarding this request: (1) the scope and timing of production; and (2) compliance with HIPAA given the nature of the Court's order, which concerns production of protected health information (“PHI”) for tens of thousands of consumers.

First, with request to the scope, manner and timing of production, the Pharmacy Defendants note for the Court that production of consumer identities—which is what the Pharmacy Defendants believe Plaintiffs seek—is not necessarily as simple as “un-redacting” the Pharmacy Defendants' prior production of dispensing data. As Plaintiffs will note in reviewing these productions, not every Pharmacy's production included redactions; some productions were simply made without PHI and with identification of individual consumers by separate identification numbers that do not constitute PHI. Other Pharmacy Defendants' productions may have included some consumer-identifying information, but not the fields Plaintiffs may seek (which have not yet been disclosed to the Pharmacy Defendants). Plaintiffs seemed to contemplate that it may be necessary to confer on these issues; the Pharmacy Defendants agree. With leave of the Court, the Pharmacy Defendants request additional time to confer with Plaintiffs regarding what information has been produced, and what information Plaintiffs seek, so that they can best evaluate how to proceed. The Pharmacy Defendants propose that the parties confer on these issues and report back to the Court at the end of May with respect to (1) the plan for production of such data, including any concerns or disputes the parties may have on this issue; and (2) the timing of such productions, which the parties can evaluate once the full scope of the requests and next steps are clear. As with the other categories of discovery, above, the Pharmacy Defendants respectfully submit that affording the parties additional time to work through these issues—and affording the Pharmacy Defendants additional time to produce this data, which is incredibly voluminous and challenging to work with—will not delay the other proceedings contemplated by the Court.

Second, HIPAA requires the retailers to “make reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended...disclosure[.]” 45

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C.F.R. § 164.502(b). And while the Pharmacy Defendants may produce PHI in response to a court order, their disclosures are limited to the information “expressly authorized” by such order. 45 C.F.R. § 164.512(e)(1)(i) (“A covered entity may disclose protected health information in the course of any judicial or administrative proceeding: (i) In response to an order of a court or administrative tribunal, provided that the covered entity discloses only the protected health information expressly authorized by such order.”). If the information Plaintiffs seek is PHI, the Pharmacy Defendants have significant concerns that the current order does not specifically permit disclosure of PHI. Indeed, the Pharmacy Defendants are not on notice and do not know precisely what information Plaintiffs seek and, if it is PHI, what efforts can be made to assure that the production constitutes the minimum disclosure necessary. *See* 45 C.F.R. 164.502(b) (requiring disclosing party to “make reasonable efforts to limit [PHI] to the minimum necessary to accomplish the intended ... disclosure”). The Pharmacy Defendants do not know what “retailer identifiers” Plaintiffs seek, as ordered by the Court—and so the Pharmacy Defendants are unable to determine whether any production of PHI is “expressly authorized” by the Court.

Pharmacy Defendants would therefore request (1) the opportunity to meet and confer with Plaintiffs regarding the information sought to ensure that, if Plaintiffs seek PHI, any such production in response to a Court order constitutes the minimum disclosure necessary; and (2) that, if the Court’s intent in ordering the production of “retailer identifiers” is to order Pharmacy Defendants to produce PHI, then the Court clarify so using explicit and specific language as to precisely what disclosure the Court is expressly authorizing.

The Pharmacy Defendants thank the Court for its consideration of these issues.

Wholesaler Defendants. In their portion of Defendants’ April 12, 2023 submission regarding the next stages of this multi-district litigation ([ECF No. 2339](#)), Wholesaler Defendants detailed some of their objections to the discovery TPP Plaintiffs sought from them. Wholesaler Defendants also explained that they will seek discovery of the TPP Plaintiffs related to their certified unjust enrichment claim, and objected to Plaintiffs’ counsel’s suggestion that Wholesaler Defendants were prohibited from obtaining such discovery. The Court ordered broad discovery of Wholesaler Defendants by TPP Plaintiffs; Wholesaler Defendants plan to file formal objections and request for clarification of Case Management Order No. 32 with the Court. The Court did not address Wholesaler Defendants’ request for discovery in CMO 32. Wholesaler Defendants therefore request that the Court address the issue of Wholesaler Defendants’ discovery to TPP Plaintiffs at the Case Management Conference on April 26, 2023.

CMO 32 makes apparent that discovery with respect to the TPP Plaintiffs’ certified class claim of unjust enrichment is permitted and not foreclosed. While Wholesaler Defendants continue to believe that any discovery should be tethered to a defined trial that Plaintiffs propose to bring against them, CMO 32 currently permits TPP Plaintiffs to undertake certain discovery of Wholesaler Defendants, including custodial discovery and additional Rule 30(b)(6) depositions, in the absence of a specific case identified for trial. As such, Wholesaler Defendants request that the Court provide them the same opportunity to take discovery from TPP Plaintiffs on their unjust enrichment claim. Specifically, Wholesaler Defendants request that the Court permit

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them to collectively serve TPP Plaintiffs with requests for production and Rule 30(b)(6) Notices of Deposition that seek (1) fact discovery regarding the value of the VCD drugs to relevant TPP Plaintiffs, including in contract fulfillment and contract and plan renewals; and (2) fact discovery regarding the profits to the relevant TPP Plaintiffs from fulfillment of all claims in issue. Should the Court later determine that merits and damages-based expert discovery may proceed, Wholesaler Defendants will seek to serve such discovery on the TPP Plaintiffs as well. As noted in the above-referenced submission, Wholesaler Defendants propose the parties meet and confer on the language of these discovery requests, and, as has been customary in this litigation, submit the proposed requests for production and Rule 30(b)(6) Notices of Deposition to the Special Master for discussion and approval.

Plaintiffs' counsel has previously taken the position that Wholesaler Defendants' request for discovery from TPP Plaintiffs is inappropriate because "general fact discovery" is closed. The Court first rejected that argument in the context of the TPP trial case, and now the Court has eliminated that argument via issuance of CMO 32, which specifically permits discovery related to the certified class claim of unjust enrichment. Moreover, the Court permitted the discovery of Wholesaler Defendants listed in CMO 32 *at Plaintiffs' request*. ([ECF No. 2338](#).) Therefore, Wholesaler Defendants request that the Court order that Wholesaler Defendants may serve requests for production and Rule 30(b)(6) Notices of Deposition related to Plaintiffs' unjust enrichment claim.

PFS Deficiencies and Orders to Show Cause

Cases Addressed at the March 29, 2023 Case Management Conference:

The Court issued four show cause orders returnable at the April 26, 2023 Case Management Conference:

1. *Mark Czajkowski v. ZHP, et al* – 22-cv-5582
2. *Juanita Calhoun v. ZHP, et al* – 22-cv-5654
3. *Nancy Lalonde v. Torrent, et al* – 21-cv-2620
4. *Yvonne Trautman v. Aurobindo, et al* – 22-cv-5471

The issues in the *Czajkowski* and *Calhoun* matters are resolved, and the show cause orders may be withdrawn.

The parties have agreed to a stipulation of dismissal in the *Trautman* matter, which will be filed shortly, but in the interim the show cause order may be withdrawn.

The issues in the *Lalonde* matter remain unresolved and Defendants requests its dismissal.

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Second Listing Cases – Order to Show Cause Requested:

Pursuant to CMO-16, the Plaintiff Fact Sheets in the below cases are substantially incomplete and contain core deficiencies. Each of these cases were previously listed on the agenda for a prior CMC. This list was provided to Plaintiffs' leadership on April 19, 2023, and a global meet and confer was held on April 21, 2023. Defendants have also been available for further discussion as needed. Accordingly, Defendants request that an Order to Show Cause be entered in each of these cases, returnable at the next case management conference, as to why these cases should not be dismissed.

Defense counsel will be prepared to address the individual issues with respect to each of these cases, to the extent necessary, during the April 26, 2023 Case Management Conference:

First Listing Cases – Remaining Core Deficiencies:

	Plaintiff	Civil Action No.	Law Firm	Deficiencies	Deficiency Sent
1.	Deborah Bixler v. ZHP, et al.	22-cv-6653	Levin Papantonio	Need medical expenses	2/8/23
2.	Estate of Arlene Cohen v. Aurobindo, et al.	22-cv-07349	Carlson Law Firm	Largely deficient PFS	2/8/23
3.	Diane Hardwick v. Aurobindo Pharma, Ltd. et al	22-cv-06397	Fleming Nolen & Jez	No medical expenses for hospital providers	1/23/23
4.	Estate of Steven Jiles v. ZHP, et al.	22-cv-5628	Seithel Law	No PFS Filed	PFS Due – 2/19/23
5.	Donald Seifert v. Mylan, et al	22-cv-6727	Brown Chiari	No PFS Filed	PFS Due – 3/26/23

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The following Plaintiff Fact Sheets contain core deficiencies which remain unresolved. This list was provided to Plaintiffs' leadership on April 19, 2023, and a global meet and confer was held on April 21, 2023. Defendants have also been available for further discussion as needed. This is the first time these cases have been listed on this agenda. Accordingly, Defendants are not requesting orders to show cause with respect to any of the below cases at this time and will continue to meet and confer to resolve these deficiencies.

	Plaintiff	Civil Action No.	Law Firm	Deficiencies	Deficiency Sent
1.	Jace Reyes v. Walgreens, et al.	22-cv-5180	Nigh Goldenberg	Need medical expenses; Authorizations must be undated	3/30/23
2.	David Sheehan v. ZHP, et al.	23-cv-61	Nigh Goldenberg	Need medical expenses; Authorizations must be undated	3/30/23
3.	Ricky Young v. ZHP, et al.	22-cv-7210	Bernstein Liebhard	Largely deficient PFS; Authorizations have to be addressed to providers, not a blank template. Also must be undated and witnessed where necessary.	3/30/22

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4.	Jacquelyn Smason v. Doe	23-cv-194	Nigh Goldenberg	Need medical expenses; provide authorization for each provider, not blank template. Must be undated.	4/3/23
5.	Mina Cole v. ZHP, et al.	23-cv-501	Watts Guerra	Need pharmacy records; need medical records. All authorizations must be filled out to provider, not blank template. Must be undated, must be witnesses where necessary	4/3/23
6.	Rafael Feria v. Teva, et al.	23-cv-485	Nigh Goldenberg	Need pharmacy records; need billing records; Authorizations must be addressed to providers listed in PFS, not blank template. Must be undated.	4/4/23
7.	Carol Pottorff v. ZHP, et al.	23-cv-552	Fleming Nolen	Need medical expenses; Medicare authorization must be undated.	4/12/23
8.	Estate of Joseph Kreseski v. ZHP, et al.	22-cv-06374	Levin Papantonio	Need medical expenses	1/23/23
9.	Charlene Cooney v. ZHP, et al.	23-cv-626	Levin Papantonio	Need medical expenses	4/12/23
10.	Phillip Morgan v. ZHP, et al.	23-cv-166	Levin Papantonio	No PFS Filed	PFS Due – 3/12/23
11.	Thomas Fogarty v. Aurobindo, et al.	21-cv-13480	Brown Chiari	No PFS Filed	PFS Due – 3/14/23
12.	Robert Janecek v. ZHP, et al.	23-cv-538	Nabers Law	No PFS Filed	PFS Due – 3/31/23

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13.	George Cook v. ZHP, et al.	23-cv-643	Nabers Law	No PFS Filed	PFS Due – 4/10/23
14.	Byron Wrigley v. Aurobindo, et al.	23-cv-831	Nigh Goldenberg	No PFS Filed	PFS Due – 4/13/23
15.	Terrance Byers v. ZHP, et al.	23-cv-847	Levin Papantonio	No PFS Filed	PFS Due – 4/14/23
16.	Richard Parks v. ZHP, et al.	23-cv-857	Levin Papantonio	No PFS Filed	PFS Due – 4/14/23

Respectfully Submitted,



Jessica Davidson

cc: All counsel of record (via ECF)